

REMARKS

This is in response to the Office Action dated December 12, 2005 rejecting claims 1-13 and 29-33, and objecting to claims 14 and 28. No claims are amended herein. Claims 1-14 and 28-33 are thus pending.

**Rejection Under 35 U.S.C. 102**

The Examiner rejects claims 1-3, 7-8, 10-11 and 29-33 under 35 USC 102(b) as being anticipated by Edwards (U.S. Pat. No. 6,006,755; "the '755 patent" hereinafter). The rejection is respectfully traversed for the reasons set forth below.

The standard for anticipation under U.S.C. §102 is that each and every element of the claim must be found in the cited reference. *In re Marshall*, 198 USPQ 344 (CCPA 1978).

Claim 1 recites an electrode deployment apparatus for treatment of tissue in a body lumen, the apparatus comprising:

a plurality of electrodes arranged on a surface of a dimensionally stable support at a pre-selected electrode density; and

an expansion member coupled to the support to deploy and selectively expose a portion of the electrode surface while shielding a remaining portion and maintaining the electrode density.

Applicants submit that the reference fails to teach each and every element of claim 1 or its dependent claims.

The Action states that the '755 patent discloses an electrode deployment apparatus for treatment of tissue in a body lumen, the apparatus comprising a plurality of electrodes arranged on a surface of a dimensionally stable support at a pre-selected electrode density (citing FIG. 5B).

The Action goes on to allege that the '755 patent also discloses selectively exposing a portion of

(citing FIG. 13). Applicants respectfully disagree.

Even if it can be argued that the '755 patent discloses exposing support mounted electrodes having given electrode densities before and after deployment, by way of an expansion member, nevertheless, it is neither disclosed nor suggested by the reference that exposing the electrodes constitutes "maintaining the electrode density" of the electrodes as presently claimed. This position is supported by the following.

The '755 patent discloses methods of using an apparatus to diagnose and treat sphincters and/or a stomach including an expandable mapping and/or treatment assembly moveable between contracted and expanded positions by an operating physician (see e.g., column 6, lines 19-32). An "expansion device 55, which can be a balloon, is coupled to an interior or exterior of [the] basket assembly 50" of the apparatus (see e.g., column 8, lines 16-18). As shown, for example, in FIG. 5B and FIG. 13, "electrodes 85 can be in the shape of needles and of sufficient sharpness and length to penetrate into smooth muscle" (column 10, lines 29-31). As shown in FIG. 13, where the electrodes are needle electrodes, the "needle electrodes 90 are attached to arms 44 and have an insulating layer 92, covering an insulated segment 94 except for an exposed segment 95" (see e.g., column 10, lines 33-35). "[N]eedle electrodes 90 are deployed by expansion of the basket assembly 50" from a contracted to an expanded configuration (column 10, lines 49-54; and FIGS. 14A-B). Importantly, as illustrated in FIGS. 14A-B, the electrode size and spacing of the deployable needle electrodes is shown as physically changing thereby altering electrode density when the supporting basket assembly is converted between contracted and expanded configurations.

In contrast, the presently claimed apparatus can "selectively expose a portion of the electrode surface while shielding a remaining portion and maintaining the electrode density." As discussed above, the '755 patent teaches away from this by disclosing electrodes physically changing in regard to both size and spacing when deployed.

Thus, by teaching that the electrode density is not maintained upon exposing a portion of the electrode surface while shielding a remaining portion, the '755 patent teaches away from the present invention. Hence, each and every element of the present invention as recited in claim 1 is not taught or suggested by the '755 patent.

For the foregoing reasons, Applicants respectfully requests that the rejection of claim 1 be withdrawn. Because the claims dependent from claim 1 (claims 2-14 and 28-33) include further limitations in addition to those recited in claim 1, Applicants believes that all depending claims are also allowable over the cited reference of record. Reconsideration of this rejection is respectfully requested.

#### **Rejection Under 35 U.S.C. 103**

The Examiner rejects claim 9 under 35 USC 103(a) as being unpatentable over the '755 patent.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

For the same reasons as recited above under §102(b) above, the '755 patent fails to teach, or suggest each and every element of claim 9 which depends from claim 1. Specifically, the reference does not teach or suggest the claim 1 limitation: "selectively expose a portion of the

electrode surface while shielding a remaining portion and maintaining the electrode density.” Furthermore, since the reference provides no suggestion or motivation to modify the reference and there would be no expectation of success in so doing, a prima facie case of obviousness cannot be shown. For the foregoing reasons, Applicants respectfully requests that the rejection of claim 9 be withdrawn.

The Examiner further rejects claims 1-13, 29-30, and 32-33 under 35 U.S.C. 103(a) as being unpatentable over Rioux (U.S. Pat. No. 6,954,611 B2; hereinafter “the ’611 patent”) in view of Wang (U.S. Pat. No. 5,462,545; hereinafter “the ’545 patent”).

Applicants traverse the rejection since the references alone or in combination fail to teach or suggest each and every element of claim 1, no suggestion or motivation to combine or modify the references exists, and there would be no expectation of success in doing so. Specifically, the references alone or in combination fail to disclose or suggest a deployment of plurality of electrodes while maintaining electrode density.

The Action states that although a plurality of electrodes can be used in the invention of the ’611 patent, the reference does not disclose their arrangement. In fact, as shown, for example, in FIGS. 13 and 14, the ’611 patent discloses two opposing RF ablation electrode arms that are described as electrically conductive, as well as collapsible and expandable (see e.g., column 9, lines 19-27). Applicants respectfully submit that the “multiple ablation elements” disclosed at column 2, lines 42-46 of the ’611 patent are clearly in reference to the “pair of opposing RF ablation electrode arms 188” disclosed at, for example, column 9, lines 19-27 and 38-45, and as shown in FIGS. 11, 12B-G, 13 and 14. Nothing in the reference suggests otherwise and a skilled artisan would logically come to such a conclusion.

Importantly, in the embodiment of the invention illustrated in FIGS. 11, 12B-G, 13 and 14, the entire structure of the arms are described as electrodes “that are composed of a suitably electrically conductive and resilient material, such as, e.g., stainless steel.” and that “can be

configured in either a monopolar or a bipolar arrangement” (column 9, lines 38-40). In another embodiment of the invention, as shown in FIGS. 2 and 3, the '611 patent discloses “an expandable/collapsible RF ablation electrode...comprising a conically shaped wall 136 that is composed of a suitable electrically conductive and resilient material, such as, e.g., stainless steel” (see e.g., column 5, lines 60-63 and column 6, lines 15-29). Again, the reference indicates that the entire structure, here comprising a conically shaped wall, is the ablation electrode. Applicants submit that the disclosed electrode structures, either arms or a structure comprising a conically shaped wall, are the electrode per se. Nothing disclosed in the reference teaches otherwise.

Next, the Action alleges that the '611 patent discloses “a self-expanding support to deploy and selectively expose a portion of the electrode surface while shielding a remaining portion and maintaining the electrode density.” Applicants respectfully disagree.

As mentioned above, the '611 patent discloses two embodiments having electrodes capable of expanding/collapsing. However, although the reference arguably might disclose deployment including selective exposure of a portion an electrode surface, nevertheless, it is neither disclosed nor suggested that exposing the electrodes constitutes “maintaining the electrode density” of the electrodes as presently claimed. This position is supported by the following.

Applicants respectfully submit that the '611 patent teaches away from “maintaining the electrode density” of the electrodes. Specifically, the reference discloses that in the case of electrode arms, the electrode arms are collapsible “inward” and “expand outward” (see e.g., column 9, lines 19-27 and FIGS. 13 and 14). Furthermore, the disclosed pair of electrode arms “collapse and expand, thereby varying the curvature of the arms” (see e.g., column 9, lines 41-45). Additionally, where a balloon is included, the balloon can expand, thereby “hinging the arms 434 outward against the wall of the vessel 170” (see e.g., column 17, lines 20-23 and FIG. 12D). As such, in each case wherein exposure (deployment) of the electrodes is disclosed, either

outward expansion, varying the curvature or hinging outward of the electrode arms is disclosed. With respect to the embodiment of an RF ablation electrode comprising a conically shaped wall, “longitudinal translation of the catheter member 120 relative to the catheter sheath 110 in a distal direction 132 deploys the ablation electrode 128 out of the axial opening” (see e.g., column 6, lines 6-9 and FIG. 1). Thus, as shown in FIG. 1, in this embodiment deployment of the electrode out of the axial opening results in a outward expansion of the electrode. Accordingly, in every case disclosed in the '611 patent the electrode size and spacing (where multiple electrode arms are involved) physically changes, as opposed to maintaining size and spacing (electrode density) upon deployment of the electrode(s).

In contrast, for the same reasons as discussed above regarding maintaining electrode size and spacing (electrode density) under §102(b), the presently claimed apparatus can “selectively expose a portion of the electrode surface while shielding a remaining portion and maintaining the electrode density” of a plurality of electrodes. As discussed above, the '611 patent teaches away from “maintaining the electrode density” by disclosing electrodes physically changing when deployed in regard to both size and spacing (where multiple electrode arms are involved). Hence, each and every element of the present invention as recited in claim 1 is not taught or suggested by the '611 patent.

Turning to the '545 patent, the Action states that it would have been obvious to one of ordinary skill in the art to have arranged the plurality of electrodes of the '611 patent on the surface of the dimensionally stable support at a pre-selected electrode density in view of the teachings of the '545 patent. Applicants respectfully submit that this point is moot in light of the above arguments since the '545 patent, like the '611 patent, fails to teach or suggest the claim 1 limitation: “selectively expose a portion of the electrode surface while shielding a remaining portion and maintaining the electrode density.”

As such the '611 patent and the '545 patent either alone or in combination fail to teach or suggest each and every element of the presently claimed invention. Furthermore, there is no

suggestion or motivation to combine the references and there would be no reasonable expectation of success in so doing. In sum, the criteria of a *prima facie* case of obviousness have not been met.

For the foregoing reasons, Applicants respectfully requests that the rejection of claim 1 be withdrawn. Because the claims dependent from claim 1 (claims 2-13, 29-30, and 32-33) include further limitations in addition to those recited in claim 1, Applicants believe that all depending claims are also allowable over the cited reference of record. Reconsideration of this rejection is respectfully requested.

CONCLUSION

Applicants earnestly believe that the application is in condition for allowance, and respectfully request Examiner to expedite prosecution of this patent application to issuance. Should Examiner have any questions, the Examiner is encouraged to telephone the undersigned.

The Commissioner is authorized to charge any additional fees which may be required, including petition fees and extension of time fees, to Deposit Account No. 23-2415 (Docket No. 28791-704.201).

Respectfully submitted,

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